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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,828	09/29/2000	Thomas J. Cummins	CDS-266	1041

7590 10/19/2004
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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/675,828	CUMMINS ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004 and 29 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,29,33 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28,29,33 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/31/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to amendments filed July 1 and July 29, 2004. Claims 28, 29, 33 and 36-40 were previously pending. Applicants amended claims 37 and 40. Claims 28, 29, 33 and 36-40 are pending and will be examined.
2. Applicants' amendments overcame the following rejections: rejection of claims 37-40 under 35 U.S.C. 112, second paragraph.
3. The declaration under 37 C.F.R. 1.131 filed on July 1, 2004 under 37 CFR 1.131 is sufficient to overcome the Frank et al. reference. The Applicants are notified that the rejection of claims 28, 33, 36-38 and 40 as being anticipated by Frank et al. was incorrectly made under 35 U.S.C. 102(b). The Frank et al. reference was published in July of 1992, whereas Applicants' priority date is May 14, 1993, therefore, the rejection should have been made under 35 U.S.C. 102(a). Therefore, the declaration filed by Applicants is proper and sufficient to overcome the Frank et al. reference. Applicants' declaration overcame the rejection of claims 28, 33, 36-38 and 40 as anticipated by Frank et al. and the rejection of claims 29 and 39 over Frank et al. and Picone et al.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on March 31, 2004 was filed after the mailing date of the non-final office action on December 29, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.
5. Applicants' submission of the IDS necessitated new grounds for rejection.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 28, 29, 33 and 36-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of U.S. Patent No. 6,709,813.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 18 of the U.S. Patent No. 6,709,813 is drawn to a method of amplification and detection of human cytomegalovirus (hCMV) DNA by amplification of the sample with two hCMV specific primers, which are positioned on the opposite strands of DNA and separated by from 90 to 400 nucleotides, and two primers specific for a different target or hCMV, which are positioned on the opposite strands of DNA and separated by from 90 to 400 nucleotides, and wherein the primers have melting temperatures (T_m s) within the range from about 65 to 74 °C and all of the primers' T_m s are within about 5 °C of each other, and wherein the first and second primers have nucleotide lengths within 5 nucleotides of each other and wherein the third and fourth primers have nucleotide

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lengths within 5 nucleotides of each other. The method of claim 18 (part A) differs from the method of claims 33 and 37 of the instant application in that it is a species of the claims 33 and 37 but fails to disclose the formula according to which the T_m s were calculated. However, the portion of the U.S. Patent No. 6,709,813 that supports the determination of T_m s lists the formula used in claims 33 and 37. Therefore one would have been motivated to calculate the T_m s using the formula presented in the U.S. Patent No. 6,709,813. Further, the limitations of claims 28 and 38 include additional, third, set of primers. Multiplexing amplification reactions was well known in the art at the time of the invention, therefore it would have been obvious to one of ordinary skill in the art to have included an additional set of primers to amplify, for example, an internal control present in the reaction mixture. Limitations of claims 29 and 39 are anticipated by part B of claim 18.

Claim 19 of the U.S. Patent No. 6,709,813 is drawn to a method of amplification and detection of human cytomegalovirus (hCMV) DNA by amplification of the sample with two hCMV specific primers, which are positioned on the opposite strands of DNA and separated by from 90 to 400 nucleotides, and two primers specific for a different target or hCMV, which are positioned on the opposite strands of DNA and separated by from 90 to 400 nucleotides, and wherein the primers have melting temperatures (T_m s) within the range from about 65 to 74 °C and all of the primers' T_m s are within about 2 °C of each other, and wherein the first and second primers have nucleotide lengths within 5 nucleotides of each other and wherein the third and fourth primers have nucleotide lengths within 5 nucleotides of each other. The method of claim 19 differs from the method of claims 36 and 40 of the instant application in that it is a species of the claims 36 and 40 but fails to disclose the formula according to which the T_m s were calculated. However, the portion of the U.S. Patent No. 6,709,813 that supports the determination of T_m s lists the formula used in claims 33 and

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37. Therefore one would have been motivated to calculate the T_m s using the formula presented in the U.S. Patent No. 6,709,813.

Allowable Subject Matter

8. Claims 28, 29, 33 and 36-40 are free of prior art, but are rejected for reasons given above.

Conclusion

9. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 31, 2004 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS

October 13, 2004



JEFFREY FREDMAN
PRIMARY EXAMINER

10/13/04